

Sub  
B-0001

8. (Amended) The method according to claim 7, wherein a preparing treatment of at least one corticosteroid is administered prior to the treatment with the combination of agonist and addictive drug.

9. (Amended) The method according to claim 7, wherein the treatment with the composition of agonist and addictive drug is followed by the administration of an addictive drug or a pharmacodynamic equivalent thereof.

10. (Amended) The method according to claim 7, wherein the treatment with the composition of agonist and addictive drug is followed by a forced application of an addictive drug or a pharmacodynamic equivalent thereof.

Please add the following claim:

11. (New) The pharmaceutical composition according to claim 5, wherein the second addictive drug is an opioid.

REMARKS

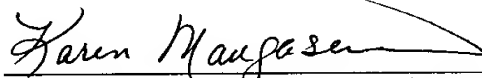
Applicant has amended the specification to set forth a priority claim under 35 U.S.C. § 120 to an earlier filed application. Applicant has also amended the specification to recite the terms "BACKGROUND OF THE INVENTION", "SUMMARY OF THE INVENTION" and "DETAILED DESCRIPTION OF THE INVENTION".

Applicant has canceled claim 1 and added claim 11. Support for added claim 11 may be found, e.g., in claim 5 as originally filed. Applicant has amended claims 2-10 to conform to United States Patent and Trademark Office practice. None of these amendments adds new matter, none of these amendments narrow the scope of the claims, and

applicant reserves the right to prosecute any matter which may have been canceled through amendments of the claims herein.

For the convenience of the Examining Division, applicants have formatted the application to include line numbering. Applicant requests entry of the amendments and allowance of the claims.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)  
Karen Mangasarian (Reg. No. 43,772)  
Attorney for Applicant  
FISH & NEAVE  
1251 Avenue of the Americas  
New York, NY 10020-1104  
Tel (212) 596-9000  
FAX (212) 596-9090

09851817.050901  
T06050"ZRT5850

## APPENDIX A

### IN THE SPECIFICATION

Page 1, immediately after the title:

Under 35 U.S.C. §§ 120 and 365(c), this application claims the benefit of copending international application PCT/EP99/08598, filed November 9, 1999, designating the United States, the disclosure of which is incorporated herein by reference in its entirety.

### BACKGROUND OF THE INVENTION

The present invention relates to the use of agonists of the glucocorticosteroid and/or mineralo-corticosteroid receptors, in particular corticosteroids, for the treatment of addictive diseases, a pharmaceutical preparation for the treatment of addictions and a method for the treatment of addictions.

Page 7:

### SUMMARY OF THE INVENTION

It is desirable to name a method of treatment, wherein the loss of control can be reversed so that the previously addicted patient finds himself in the status quo ante. In order to achieve this aim, the task of the present invention was to name substances which make medical treatment of an addictive disease possible. The medical drugs should be useable in a therapy with a causal effect.

09854837.050904

Page 13:

DETAILED DESCRIPTION OF THE INVENTION

Surprisingly it was found that with administration of agonists of the glucocorticosteroid and/or mineralcorticosteroid receptors, in particular corticosteroids, in a certain sequence to the forced administration of an addictive drug or the pharmacodynamic equivalent thereof, the development of

IN THE CLAIMS

Immediately under the heading "CLAIMS", insert -- What is claimed is --.

2. (Amended) [Use] The method according to claim [1] 7, wherein the [agonists are] agonist is a corticosteroid [corticosteroids] or a [their] pharmacodynamic equivalent thereof.

3. (Amended) [Use] The method according to claim 2, wherein the [corticosteroids] corticosteroid is selected from the group consisting of [are the compounds] cortisol, cortisone, cortisone acetate, corticosterone, prednisolone, prednisone, prednylidene, methylprednisolone, triamcinolone, betamethasone, dexamethasone, paramethasone, fluorcortolone, deflazacort, cloprednol and fludrocortisone, [the] a pharmacodynamic equivalent thereof or a combination [combinations] thereof.

4. (Amended) [Use] The method according to any one of claims [1-3] 2, 3 or 7, wherein the addictive [diseases are] disease is selected from the group [comprising] consisting of opiate dependency, [psychostimulants] psychostimulant dependency,

0951217 050901

hallucinogen and entactogen dependency, [particularly] amphetamine dependency, LSD dependency, and MDMA (Ecstasy) dependency, nicotine addiction, cannabinoid dependency, cocaine addiction, "Crack" addiction, [(inclusive "Crack") and/or] alcoholism [as well as] or polytoxicomanic addiction [using said forms of addiction].

5. (Amended) A pharmaceutical composition [Pharmaceutical compositions] for the treatment of an addictive [diseases containing the] disease comprising:

a. an addictive drug responsible for the addictive disease [,] or a [the] pharmacodynamic equivalent thereof; or [another] a second addictive drug or [the] a pharmacodynamic equivalent thereof [(particularly of an opioid)]; and

b. at least one agonist selected from the group consisting of a [the] corticosteroid [and/or] receptor, a mineralo-corticosteroid receptor or a combination thereof [receptors, particularly a corticosteroid].

6. (Amended) The pharmaceutical [Pharmaceutical] composition according to claim 5 [which contains] wherein the addictive drug or [the] a pharmacodynamic equivalent thereof is in a high dose [dosis, i.e. on the threshold of undesired side effects hazardous to health] and wherein the maintenance dose of at least one corticosteroid agonist is in the amount of 0.5-100 mg/day [as the maintenance dosage] and [a] 2 to 10 times higher amount for the initial dosage for a patient having a body weight of 60-80 kg.

7. (Amended) A method of treating an [Method for the treatment of] addictive [diseases by administration of] disease caused by an addictive drug

0951817 050901

or in connection with the addictive drug comprising the step of administering a composition comprising:

a. at least one agonist selected from the group consisting of a [the] corticosteroid receptor, a [and/or] mineralo-corticosteroid receptor, or a combination thereof; [receptors, particularly a corticosteroid] and

b. the [an] addictive drug or [the] a pharmacodynamic equivalent thereof [, wherein an addict is administered a combination of agonists of the corticosteroid and/or mineralo-corticosteroid receptors, particularly corticosteroid and addictive drug or the pharmacodynamic equivalent thereof].

8. (Amended) The method [Method] according to claim 7, wherein a preparing treatment of at least one corticosteroid is administered prior to the treatment with the combination of agonist and addictive drug [combined application, a preparing treatment with at least one corticosteroid is carried out].

9. (Amended) The method [Method] according to claim 7, wherein [after the application of the combination] the treatment with the composition of agonist and addictive drug is followed by the administration of [of corticosteroid and addictive drug or the pharmacodynamic equivalent thereof,] an addictive drug or [the] a pharmacodynamic equivalent thereof [is administered].

10. (Amended) The method [Method] according to claim 7, wherein the treatment with the composition of agonist and addictive drug is followed by [after the combined application a follow-up treatment with] a

09851817 050901  
T06050 2782860

forced application of an addictive drug or [the] a  
pharmacodynamic equivalent thereof [is carried out].

11. (New) The pharmaceutical composition  
according to claim 4, wherein the second addictive drug  
is an opioid.

09851317 050901  
T06050 4T8T860